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10 VIVITRO LABS, INC.

11 UNITED STATES DISTRICT COURT
12
13 CENTRAL DISTRICT OF CALIFORNIA

14 BIOMEDICAL DEVICE
15 CONSULTANTS & LABORATORIES
16 OF COLORADO, LLC

17 Plaintiff,

18 v.

19 VIVITRO LABS, INC.,
20 Defendants.

Case No.: 2:23-CV-04291-RGK-E

Hon. Judge R. Gary Klausner

**DEFENDANT VIVITRO LABS,
INC.'S ANSWER, AFFIRMATIVE
DEFENSES, AND
COUNTERCLAIMS TO
PLAINTIFF'S COMPLAINT**

1 Defendant ViVitro Labs Inc. (“ViVitro” or “Defendant”), by and through its
2 undersigned counsel, hereby responds to the Complaint (ECF No. 1) of Plaintiff
3 Biomedical Device Consultants & Laboratories of Colorado, LLC (“BDC” or
4 “Plaintiff”) as follows:

5 **VIVITRO’S ANSWER**

6 ViVitro responds to the individually-numbered paragraphs in BDC’s Complaint
7 as follows:

8 **NATURE OF ACTION**

9 1. ViVitro lacks sufficient knowledge or information to form a belief as to
10 the truth of the allegations that BDC is the owner of the Patent in paragraph 1 of the
11 Complaint and therefore denies those allegations. ViVitro admits that a copy of the
12 ’935 Patent is attached to the Complaint as Exhibit A. ViVitro denies the remaining
13 allegations of this paragraph.

14 2. ViVitro lacks sufficient knowledge or information to form a belief as to
15 the truth of the allegations in this paragraph and therefore denies those allegations.

16 3. ViVitro admits that BDC is a supplier and provider of testing services for
17 prosthetic heart valve products. ViVitro admits that it is developing a new heart valve
18 durability tester. Except as expressly admitted above, ViVitro denies all other
19 allegations in this paragraph of the Complaint.

20 4. ViVitro admits that it received correspondence from BDC alleging
21 infringement. ViVitro denies that such correspondence included “a detailed
22 explanation of infringement.” ViVitro admits that it refused to cease any conduct with
23 respect to its forthcoming product, but denies any such conduct infringes any valid
24 claim of the ’935 Patent.

25 5. ViVitro lacks sufficient knowledge or information to form a belief as to
26 the truth of the allegations about Plaintiff’s motives for filing this action and therefore
27 denies the allegations of this paragraph of the Complaint.
28

THE PARTIES

6. ViVitro lacks sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph and therefore denies those allegations.

7. Admitted.

8. ViVitro admits that BDC and ViVitro are competitors in the field of cardiac-related medical device testing equipment, and testing services. Except as expressly admitted above, ViVitro denies any other allegations in this paragraph of the Complaint.

JURISDICTION AND VENUE

9. The allegations in paragraph 9 are conclusions of law, rather than statements of fact, to which no response is required. To the extent a response is required, ViVitro admits, based solely on the allegations of the Complaint and without admitting them as true, that the Complaint purports to allege an action for patent infringement, and that this Court has subject matter jurisdiction over such actions pursuant to 28 U.S.C. §§ 1331 and 1338(a). Except as expressly admitted above, ViVitro denies all other allegations in this paragraph of the Complaint.

10. ViVitro admits that the District Court for the Central District of California has personal jurisdiction over it in this action. ViVitro denies all other allegations in this paragraph of the Complaint.

11. ViVitro admits that venue is proper in the Central District of California but denies the legal sufficiency of BDC's claims and allegations.

THE PATENT-IN-SUIT

12. Much of the statement in paragraph 12 is not an allegation to which a response is necessary. To the extent a response is necessary, ViVitro admits this case concerns equipment used for durability or high cycle fatigue testing of heart valves. ViVitro further admits that prosthetic heart valves must meet certain regulatory standards and that the International Organization for Standardization sets standards for the testing for durability of prosthetic heart valves. ViVitro lacks sufficient

1 knowledge or information to form a belief as to the truth of the allegations regarding
2 the regulation of other medical devices and therefore denies those allegations.

3 13. Much of the statement in paragraph 13 is not an allegation to which a
4 response is necessary. To the extent a response is necessary, ViVitro admits that
5 prosthetic heart valves are tested to industry standards, where the test fluid causes the
6 valves to open and close repeatedly, and the re-circulating of test fluid simulates the
7 flow of blood in the heart. Further, ViVitro admits that durability testing has been
8 conducted on an “accelerated” basis, since long before the priority date of the asserted
9 patent, to represent the prosthetic heart valve being used for years. Except as
10 expressly admitted above, ViVitro denies all other allegations in this paragraph of the
11 Complaint.

12 14. Denied.

13 15. ViVitro admits that the written description of the Patent-in-Suit discloses
14 a device for testing heart valves at a high rate of speed. The remaining allegations of
15 this paragraph of the Complaint set forth the legal conclusions of the pleading party
16 for which no response is required. To the extent a response is required, ViVitro
17 denies the allegations of this paragraph of the Complaint.

18 16. ViVitro lacks sufficient knowledge or information to form a belief as to
19 the truth of the allegations in this paragraph and therefore denies those allegations.

20 17. ViVitro lacks sufficient knowledge or information to form a belief as to
21 the truth of the allegations in this paragraph and therefore denies those allegations.

22 **DEFENDANT’S INFRINGING PRODUCT**

23 18. ViVitro admits that it has offered to sell the ADC Heart Valve Durability
24 Tester in the United States. ViVitro denies all other allegations of this paragraph.

25 19. ViVitro admits that it has entered into at least one agreement with a
26 customer for sale of the forthcoming ADC Heart Valve Durability Tester, but ViVitro
27 denies that the customer or sale are in the United States. Accordingly, this allegation
28 is irrelevant to this action for patent infringement. Further, ViVitro admits that it has

1 not delivered the product to any customers (in the United States or otherwise). Except
2 as expressly admitted above, ViVitro denies all other allegations in this paragraph of
3 the Complaint.

4 20. ViVitro admits that its forthcoming ADC Heart Valve Durability Tester
5 is not manufactured in the United States. ViVitro admits that its representatives have
6 transported a prototype of the product to the United States on two occasions at
7 conferences/trade shows.

8 21. Admitted.

9 22. ViVitro admits that one of the features described in its brochure is the
10 inflow and outflow chamber annular compliance rings to optimize differential
11 pressure waveforms. Except as expressly admitted above, ViVitro denies all other
12 allegations in this paragraph of the Complaint.

13 23. ViVitro admits that a copy of a claim chart is attached to the Complaint
14 as Exhibit C. Except as expressly admitted above, ViVitro denies all other allegations
15 in this paragraph of the Complaint.

16 **DEFENDANT'S INFRINGING PRODUCT**

17 24. ViVitro admits that in August 2022, it received a letter from BDC
18 alleging infringement with a claim chart attached. ViVitro admits that its September
19 2022 response stated that it believed it had "corrected [BDC]'s misunderstanding
20 regarding" the accused product, but ViVitro denies that it "did not deny
21 infringement." In truth, ViVitro's September 2022 response identified specific
22 deficiencies with BDC's infringement allegations and provided multiple reasons why
23 the product does not have all the required elements of the asserted claim and stated
24 that ViVitro "does not appear to have infringed claim 1 of the '935 Patent." ViVitro
25 further avers that BDC, in subsequent correspondence, then changed its theory of
26 alleged infringement, which ViVitro likewise denied on January 31, stating,
27 "ViVitro's proposed valve tester does not infringe any valid claim of the '935 patent."
28 ViVitro denies that the prior art identified in its January 31 communication "had little

relationship to the claimed invention” for at least the reasons argued in ViVitro’s response to BDC’s motion for preliminary injunction showing why some of those references invalidate the asserted claims. Except as expressly admitted above, ViVitro denies all other allegations in this paragraph of the Complaint.

25. ViVitro admits that it has displayed and offered for sale the ADC Heart Valve Durability Tester at the TCT Conference in Boston in September 2022 and at the MD&M West Conference in Anaheim, California in February 2023. ViVitro denies that Exhibit D to the Complaint shows a page that was “listed on [ViVitro’s] website” as of March 27, 2023. Rather, Exhibit D shows on its face that the Wayback Machine captured the web page on September 26, 2022. Except as expressly admitted above, ViVitro denies all other allegations in this paragraph of the Complaint.

FIRST CAUSE OF ACTION

DIRECT INFRINGEMENT OF THE ’935 PATENT

35 U.S.C. § 271

26. The statement in paragraph 26 is not an allegation to which a response is necessary. To the extent a response is required, ViVitro incorporates by reference its response to the preceding paragraphs as though fully set forth herein.

27. ViVitro admits that the face of the ’935 Patent reflects that it was issued by the USPTO on January 19, 2016, and that it is titled “Fatigue Testing System for Prosthetic Devices.” ViVitro denies that the ’935 Patent was “duly and legally issued.”

28. Denied.

29. Denied.

30. Denied.

31. The allegations in paragraph 31 of the Complaint set forth the legal conclusions of the pleading party for which no response is required. To the extent a response is required, ViVitro denies the allegations in paragraph 31 of the Complaint.

1 32. The allegations in paragraph 32 of the Complaint set forth the legal
2 conclusions of the pleading party for which no response is required. To the extent a
3 response is required, ViVitro denies the allegations in paragraph 32 of the Complaint.

4 33. The allegations in paragraph 33 of the Complaint set forth the legal
5 conclusions of the pleading party for which no response is required. To the extent a
6 response is required, ViVitro denies the allegations in paragraph 33 of the Complaint.

7 34. The allegations in paragraph 34 of the Complaint set forth the legal
8 conclusions of the pleading party for which no response is required. To the extent a
9 response is required, ViVitro denies the allegations in paragraph 34 of the Complaint.

10 35. The allegations in paragraph 35 of the Complaint set forth the legal
11 conclusions of the pleading party for which no response is required. To the extent a
12 response is required, ViVitro denies the allegations in paragraph 35 of the Complaint.

13 36. The allegations in paragraph 36 of the Complaint set forth the legal
14 conclusions of the pleading party for which no response is required. To the extent a
15 response is required, ViVitro denies the allegations in paragraph 36 of the Complaint.

16 37. The allegations in paragraph 37 of the Complaint set forth the legal
17 conclusions of the pleading party for which no response is required. To the extent a
18 response is required, ViVitro denies the allegations in paragraph 37 of the Complaint.

19 38. The allegations in paragraph 38 of the Complaint set forth the legal
20 conclusions of the pleading party for which no response is required. To the extent a
21 response is required, ViVitro denies the allegations in paragraph 38 of the Complaint.

22 39. ViVitro admits that in August 2022, ViVitro received a letter from BDC
23 alleging infringement. Except as expressly admitted above, ViVitro denies all other
24 allegations in this paragraph of the Complaint.

25 **GENERAL DENIAL**

26 Unless expressly admitted herein, ViVitro denies each and every allegation
27 contained in Paragraphs 1 through 39 of BDC's Complaint and denies that BDC is
28 entitled to any of the relief requested in its Prayer for Relief. The unnumbered

1 “WHEREFORE” paragraph, including subparagraphs A-F, following paragraph 39 of
2 the Complaint is a prayer for relief that does not contain any allegations of fact and
3 therefore no response is required. To the extent a response is deemed necessary,
4 ViVitro denies each and every allegation and assertion listed in this paragraph,
5 including all separate sub-parts, and denies that BDC is entitled to any of the relief
6 requested.

7 **AFFIRMATIVE DEFENSES**

8 Pursuant to Federal Rule of Civil Procedure 8(c), ViVitro asserts the following
9 affirmative defenses to BDC’s allegations in the Complaint. By alleging the
10 affirmative defenses below, ViVitro does not admit that it has the burden of proof on
11 such matters or that any of the following defenses are not already at issue by virtue of
12 the forgoing responses.

13 **FIRST DEFENSE**

14 The Complaint fails to state a claim upon which relief may be granted and
15 therefore should be dismissed pursuant to Fed. R. Civ. P. 12(b)(6).

16 **SECOND DEFENSE**

17 Upon information and belief, and without prejudice to further amendment upon
18 information found during discovery, all claims of the ’935 Patent are invalid for
19 failure to satisfy the conditions of patentability as specified under one or more
20 sections of Title 35 of United States Code, including, without limitation, 35 U.S.C. §§
21 102, 103, and/or 112.

22 **THIRD DEFENSE**

23 ViVitro does not make, use, sell, offer for sale, or import into the United States,
24 and has not made, used, sold, offered for sale or imported into the United States any
25 products that infringe any valid claim of the ’935 Patent, either willfully, directly,
26 indirectly, contributorily, through the doctrine of equivalents, or otherwise, and has
27 not induced others to infringe the ’935 Patent.
28

1 **FOURTH DEFENSE**

2 BDC is not entitled to enhanced damages for willful infringement because
3 ViVitro has not engaged in any conduct that meets the applicable standard for willful
4 infringement. For example, BDC cannot demonstrate that ViVitro had the specific
5 intent to infringe the '935 Patent or that there has been any egregious conduct.

6 **FIFTH DEFENSE**

7 BDC's claims are barred, in whole or in part, by equitable doctrines, including
8 waiver, estoppel, acquiescence, patent misuse, and/or unclean hands.

9 **RESERVATION OF RIGHTS**

10 ViVitro reserves the right to add any additional defenses and counterclaims that
11 may be revealed during the course of discovery.

12 **VIVITRO'S COUNTERCLAIMS**

13 ViVitro alleges the following counterclaims against Plaintiff BDC:

14 **THE PARTIES**

15 1. ViVitro is a Canadian corporation with its principal place of business
16 located at 455 Boleskine Road, Victoria, BC, Canada V8Z 1E7.

17 2. According to the allegations in its Complaint, BDC is a Colorado limited
18 liability company with a principal place of business in Wheat Ridge, Colorado.

19 **JURISDICTION AND VENUE**

20 3. These counterclaims seek relief under the Declaratory Judgment Act 28
21 U.S.C. §§ 2201 and 2202.

22 4. This Court has subject matter jurisdiction over these Counterclaims, and
23 jurisdiction, under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

24 5. This Court has personal jurisdiction over BDC because it has subjected
25 itself to the jurisdiction of this Court by pursuing its claims in this Court.

26 6. Venue for these counterclaims is proper in this District, as concluded by
27 the District Court for the District of Colorado in transferring this action here.
28

7. Based on BDC's filing of its Complaint, and ViVidro's Answer and Affirmative Defenses to the Complaint, a true, actual, and justiciable controversy has arisen and now exists between ViVidro and BDC regarding the non-infringement and invalidity of the '935 Patent.

FIRST COUNTERCLAIM

Declaration of Non-Infringement of the '935 Patent

8. BDC has alleged in its Complaint that ViVidro's ADC Heart Valve Durability tester meets every limitation of at least Claims 1-4, 8, 9, and 12-13 of the '935 Patent, either literally or under the doctrine of equivalents. (*See* Complaint ¶ 30).

9. ViVidro does not infringe the '935 Patent because it does not make, use, offer for sale, sell, or import into the United States any product that includes each and every limitation of the claims of the '935 Patent, either literally or equivalently.

10. ViVidro seeks a declaration that ViVidro does not and has not infringed, either directly, indirectly, literally, by equivalents, contributorily, or through inducement, any claim of the '935 Patent.

SECOND COUNTERCLAIM

Declaration of Invalidity of the '935 Patent

11. ViVidro incorporates its allegations in Counterclaim paragraph 8 as though fully set forth herein.

12. One or more claims of the '935 Patent are invalid for failure to meet the "conditions for patentability" specified in 35 U.S.C. §§ 102, 103, and/or 112. The alleged inventions contained in the '935 Patent are taught by, suggested by, and/or obvious in view of, the prior art; and/or are not adequately supported by the written description of the patented invention and/or not enabled.

13. ViVidro seeks a declaration that the '935 Patent is invalid.

EXCEPTIONAL CASE

For the reasons set forth in ViVistro's Affirmative Defenses and Counterclaims, this is an exceptional case entitling ViVistro to an award of attorney fees pursuant to 35 U.S.C. § 285.

JURY DEMAND

ViVistro demands a trial by jury of all issues so triable in this action.

PRAYER FOR RELIEF

WHEREFORE, ViVistro prays for the following relief:

- A. Judgment against Plaintiff and in favor of ViVistro as to all claims for relief in the Complaint;
- B. Denial of Plaintiff's request for injunctive relief;
- C. Dismissal of the Complaint with prejudice;
- D. A declaration that ViVistro does not infringe, under any theory, any valid claim of the '935 Patent that might be enforceable;
- E. A declaration that each of the claims of the '935 Patent are invalid;
- F. A finding that this case is an exceptional case under 35 U.S.C. § 285 and an award to ViVistro of its costs and attorneys' fees incurred in this action; and
- G. Such other relief as the Court deems just and proper.

Dated: June 15, 2023

FOX ROTHSCHILD LLP
MEUNIER CARLIN & CURFMAN

By /s/ Jeff Grant
Jeff Grant
Warren J. Thomas
Attorneys for Defendant VIVITRO LABS,
INC.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that, on this 15th day of June 2023, the foregoing document was electronically filed with the Clerk of Court using the CM/ECF system, which will automatically send e-mail notification of such filing to all attorneys of record.

Dated: June 15, 2023

FOX ROTHSCHILD LLP

By /s/ Jeff Grant
Jeff Grant
Attorneys for Defendant VIVITRO LABS,
INC.